

REMARKS

This amendment is submitted in response to the Non-Final Office Action mailed April 17, 2008, in connection with the above-identified application (hereinafter, the "Office Action"). The Office Action provided a three-month shortened statutory period in which to respond, ending on July 17, 2008. Accordingly, this amendment is timely submitted.

I. Pending Claims

Claims 1-3, 5-10 and 11, of which claims 1, 9, and 11 are independent, remain pending and appear in this application for the Examiner's review and consideration. Claims 12 and 13 are cancelled. New claim 14 recites the features of claim 4 thereby cancelling claim 4. Applicant respectfully submits that no new matter has been introduced by these amendments and in the introduction of the new claim. Thus, they all should be entered at this time.

Applicant does not acquiesce in the correctness of the rejections or objections and reserve the right to present specific arguments regarding any rejected or objected-to claims not specifically addressed. Further, Applicant reserves the right to pursue the full scope of the subject matter of the claims in a subsequent patent application that claims priority to the instant application.

Claims 1, 2, 3, 9, 10 and 11 have been amended to provide better clarity and proper antecedent basis. Independent claims 1, 9 and 11 have been amended to further recite that the "energy content of the nutritional composition is between 1.4-1.6 kcal per ml of the composition" and that "the remainder of said nutritional composition comprises 40 to 80% by weight of casein, from 60-20% by weight of whey; and from 0.5 to 20 μ g of TGF- β per 100 kcal of the composition." Support for these amendments is found in the published patent application, US 2007/0042021 A1, at paragraph [0072], [0022] and [0025], respectively.

Applicant would like to thank the Examiner for her recommendation of the claim language to overcome the claim objections and indefiniteness rejection. Applicant respectfully submits that the objections and rejections based on indefinites and obviousness are overcome in view of the amendments and arguments presented in the instant response. Applicant, therefore, requests that all amendments be entered at this time and that the Examiner reconsider the present application in view of the above amendments and the following remarks.

II. Claim Objections

Claims 1, 9, and 11 have been amended to improve the syntax in accordance with the Examiner's recommendations. With respect to the objection of claim 4, as being of improper dependent form, the claim has been cancelled and its features are recited in new claim 14. In claim 10, the term "use" has been amended to the term "method." The objection of claims 12 and 13 is moot in view of the cancellation of these claims.

In view of the amendments and above remarks, Applicant respectfully requests the withdrawal of the claim objections.

III. Claim Rejection Under 35 U.S.C §112, Second Paragraph

Claims 1, 9, and 11-13 have been rejected under 35 U.S.C §112, second paragraph, as being indefinite. As suggested by the Examiner, claims 1, 9 and 11 have been amended to recite that "the remainder of said nutritional composition comprises 40 to 80% by weight of casein, from 60-20% by weight of whey; and from 0.5 to 20 µg of TGF-β per 100 kcal of the composition." Claims 12 and 13 have been cancelled thus rendering the rejection of these claims moot.

In addition, the term "symptom" in claim 11 has been substituted with the term "sign," as proposed by the Examiner.

The Examiner's suggested claim language "administering to the patient an effective amount of a nutritional composition" has been added into claims 9 and 11. Claim 12, in turn, has been cancelled, as well as claim 13 to avoid claim duplication.

In view of the foregoing and amendments, Applicant respectfully submit that claims 1-13 are no longer indefinite and the rejection of these claims should be withdrawn.

IV. Rejection Under 35 U.S.C §103

Claims 1-13 have been rejected under 35 U.S.C §103(a), as being unpatentable over WO02/083164 to Perrin et al. (referred hereinafter as "Perrin"), in view of WO99/56758 to Whyte. (referred hereinafter "Whyte"), and further in view of WO96/34614 to Read et al. (referred hereinafter "Read"). Applicant respectfully disagrees with the rejections based on the remarks provided hereinbelow.

The present invention, as set forth in amended independent claims 1, 9 and 11, as well as new independent claim 14, relates to nutritional compositions and methods of using such compositions, wherein the composition has an energy content is between 1.4-1.6 kcal per ml of the composition and includes (1) a lipid source; (2) a carbohydrate source; (3) a protein source that provides from 20 to 30% of the energy of the composition and comprises casein, whey and TGF- β ; and (4) free glutamine in a quantity such as to provide from 2 to 15% of the energy of the composition. The remainder of the nutritional composition comprises 40 to 80% by weight of casein, from 60-20% by weight of whey; and from 0.5 to 20 μ g of TGF- β per 100 kcal of the composition. The compositions of the claimed invention are for alleviating and/or reducing the side effects of chemotherapy and/or radiotherapy and for providing nutrition to cancer patients who are in the process of receiving such treatments and immediately after the periods of such treatments. With respect to new claim 14, the energy content is between 1.2 to 2 kcal per ml of the composition.

Contrary to the presently-claimed invention, Perrin, as the primary reference, generally describes a nutritional composition that contains a protein source that includes casein rich in TGF- β 2, for the prophylaxis of insulin-dependent diabetes mellitus type I in infants. See Perrin's Abstract. The energy density of Perrin's composition is between 105-130 kcal/100 ml of the composition, which is lower than that of the claimed invention. See Perrin at page 7, second full paragraph. In addition, the protein source of the nutritional diet used in the experimental study of diabetes-prone BioBreeding rats in Example 2 of Perrin is 18%. See Perrin's at page 9, paragraph 2. This value is lower than that provided by the protein source of the claimed invention, i.e., 20-30%. In addition to these differences and also acknowledged in the Office Action, Perrin's composition does not contain glutamine. Accordingly, in view of the lack of these features in Perrin's composition, Applicant respectfully submits that Perrin fails to render obvious the subject matter of claims 1-13.

To overcome Perrin's deficiencies, the Office Action applied a secondary reference, Whyte, which generally describes a food composition and methods for using such composition for changing body composition and/or physical work capacity. See Whyte's Abstract. The food composition includes colostrum or a fraction thereof having a mixture of growth factors (e.g., IGF-1, GLP-2 analogue) and a carrier. See Whyte at page 4, lines 30-31 and page 13, lines 13-15. Other than proteins, the food composition may also include supplements such as minerals, salts, electrolytes, vitamins, carbohydrates, amino acids, fats and other nutrients. Whyte at page 7, line 5 to page 8, line 6. The food composition may include casein, which is colostrum-derived. Whyte however, did not mention the inclusion of whey protein in its composition. Instead, whey protein powder (60 g/day) is used as a placebo to compare the favorable effects of bovine colostrum (60 g/day) in the reduction of body fat and improvement of running performance on Endurance Athlete (EA). See Whyte's Example 2, at page 21. Thus, Whyte, similar to Perrin, also fails to describe or even suggest the use of a composition having an energy content of 1.4-1.6 kcal/ml of the composition and a protein source that provides 20-30 % energy of the composition. Whyte did mention the use of glutamine but fails to provide a concentration range to be used in the food composition. Thus, one of ordinary skill in the art, upon reading the Whyte reference, would not know how to combine Whyte's teachings with Perrin, to arrive at the claimed invention. Applicant respectfully submits that Whyte fails to cure the aforementioned deficiencies of the primary reference, and that Perrin nor Whyte, taken individually or in combination, disclose or suggest the claimed nutritional composition, as set forth in amended claims 1, 9 and 11, as well as the claims that depend therefrom and new claim 14.

Because neither Perrin nor Whyte discloses or suggests the use of their compositions for chemotherapy and/or radiotherapy, The Office Action applied a tertiary reference, Read, which generally describes and suggests a method of preventing, ameliorating and/or treating damage to the lining of the alimentary tract resulting from chemotherapy and/or radiation. The method includes the administration of an effective amount of milk product extract and a pharmaceutically- or veterinarily-acceptable diluent, carrier or excipient. The milk product extract, according to Read, may be a cheese whey extract, colostrum whey extract, skim milk extract, acid (casein) whey extract. Additional one or more growth factors such as IGF-1, IGF-2, TGF- β , EGF, and etc. may be employed. See Read, at page 7, lines 28-32.

Contrary to the claimed invention, and as with Whyte, Read fails to describe or even suggest the claimed nutritional compositions or methods of making such compositions that have an energy content of 1.4-1.6 kcal/ml of the composition and a protein source that provides 20-30 % energy of the composition. Moreover, Read also fails to describe and suggest the use of glutamine in her composition, as required by the presently-claimed invention. Accordingly, both Whyte and Read fail to cure the above-mentioned deficiencies of Perrin. Moreover, even if Perrin is combined with Whyte and Read, one of ordinary skill in the art would still not be able to arrive at the claimed nutritional compositions and methods of using such compositions, as encompassed in claims 1, 9 and 11, as well as the claims that depend therefrom and new claim 14.

In view of the foregoing remarks and claim amendments, Applicant respectfully submits that Perrin, Whyte and Read, as discussed above, either alone or in combination, fail to disclose or suggest the subject matter of presently-claimed invention. See MPEP 2143.03. ("To establish *prima facie* obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art").

Furthermore, Applicant respectfully submits that the Examiner has failed to establish any motivation to combine Sekimoto and the cited secondary and tertiary references. The Federal Circuit has repeatedly emphasized that evidence of a motivation to combine must accompany a challenge based on multiple references. See *In re Dembiczak*, 175 F.3d 994 (Fed. Cir. 1999) and *ATD Corp. v. Lydall, Inc.*, 159 F.3d 534 (Fed. Cir. 1998). See also MPEP §2143.01 (The prior art must suggest the desirability of the claimed invention). A statement that various combinations of the prior art to meet the claimed invention would have been within the ordinary skill in the art is not alone sufficient to establish a *prima facie* case of obviousness.

Accordingly, Applicant respectfully requests that the §103(a) rejection of claims 1-13 be reconsidered and withdrawn in view of the above remarks and clarifications of the claims.

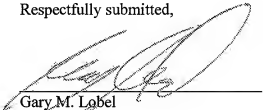
CONCLUSION

For at least the reasons set forth above, this application is in condition for allowance. Favorable consideration and prompt allowance of the claims are earnestly requested. Should the Examiner have any questions that would facilitate further prosecution or allowance of this application, the Examiner is invited to contact the Applicant's representative designated below.

The Commissioner is hereby authorized to charge any additional fees under 37 CFR §1.17 which may be required, or credit any overpayment, to deposit account no. 50-4498 in the name of Nestle Nutrition.

Respectfully submitted,

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